Human Papillomavirus 9-valent Vaccine (HPV 9)

Date: January 4, 2018

Rationale for update: Two-dose schedule for immunocompetent individuals ages 9-14 years of age inclusive.

Implementation date: September 1, 2018

Please consult the Product Monograph¹ for further information about the vaccine.

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<th>GARDASIL®9</th>
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<td>Manufacturer</td>
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| Licensed for | • Females 9 years of age up to and including 45 years of age.  
• Males 9 years up to and including 26 years of age. |
| Off-license use | None |
| Indications for use of provincially funded vaccine | • Grade 6 students – routine immunization program.  
• Students eligible to receive vaccine in Grade 6 continue to be eligible to receive the vaccine until the end of Grade 12 if they present to public health.  
• Individuals 17 to 26 years of age biologically male at birth who have sex with individuals biologically male at birth.²  
• Hematopoietic Stem Cell Transplantation (HSCT) recipients: See Immunization for Child Hematopoietic Stem Cell Transplant Recipients.  
• Solid organ transplant (SOT) candidates and recipients: See Immunization for children Expecting Solid Organ Transplant after 18 Months of Age (Catch-up Schedule) and Immunization for Adult Solid Organ Transplant Candidates and Recipients. |
| Dose | 0.5 mL |
| Route | Intramuscular injection |
| Schedule | Immunocompetent and non HIV infected individuals ages 9-14 years of age inclusive (2-dose series):²  
Dose 1: day 0  
Dose 2: six months after dose 1  
Immunocompromised and/or HIV infected individuals ages 9-14 years of age inclusive (3-dose series):²  
• Dose 1: day 0  
• Dose 2: two months after dose 1  
• Dose 3: six months after dose 1  
Individuals 15 years of age and older (3 dose series):²  
• Dose 1: day 0  
• Dose 2: two months after dose 1  
• Dose 3: six months after dose 1 |
| Notes: | The number of recommended doses in a series is based on the age at administration of the first dose. In immunocompetent individuals 15 years of age and older who received the first dose between 9 to less than 15 years of age a two-dose schedule can be used, with the second dose administered at least 6 months after the first dose.²³ |
In a two-dose schedule the minimum interval is 24 weeks between the first and second dose.\textsuperscript{2,3}.

In a three-dose schedule the minimum interval between the first and second doses of vaccine is 4 weeks, the minimum interval between the second and third doses of vaccine is 12 weeks, and the minimum interval between first and last doses is 24 weeks.\textsuperscript{4}

Eligible individuals, who began their series with GARDASIL\textsuperscript{®} (HPV4) can complete the series using GARDASIL\textsuperscript{®}9.\textsuperscript{3} However, they should be advised that protection against HPV types 31, 33, 45, 52, and 58 cannot be ensured.\textsuperscript{2}

There is insufficient evidence at this time to recommend, at a population level, the re-immunization with HPV9 of individuals who have completed an immunization series with another HPV vaccine.\textsuperscript{2}

### Contraindications
- Known severe hypersensitivity to any component of GARDASIL\textsuperscript{®}9.
- Anaphylactic reactions to a previous dose of vaccine.

### Precautions
- None identified

### Possible reactions

#### Local reactions:
- Pain, swelling, erythema, and pruritus at the injection site.\textsuperscript{1}

#### Systemic reactions:
- Fever, nausea, dizziness, headache, fatigue, myalgia, diarrhea and upper abdominal pain.\textsuperscript{1}
- The following events have been reported from post-marketing surveillance of GARDASIL\textsuperscript{®} and may also be seen in post-marketing with GARDASIL\textsuperscript{®}9: anaphylaxis, bronchospasm, autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy, acute disseminated encephalomyelitis, Guillain-Barré syndrome, motor neuron disease, paralysis, syncope, transverse myelitis, pancreatitis, pulmonary embolus, asthenia, chills, fatigue, malaise, cellulitis, urticaria, vomiting, diarrhea, myalgia, arthralgia and death.\textsuperscript{1}

Refer to: Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.\textsuperscript{5}

### Pregnancy
HPV vaccine is not recommended for use in pregnancy or women who become pregnant before the completion of the three-dose schedule. If pregnant, immunization with the remaining doses of vaccine should be delayed until after delivery.\textsuperscript{1,2} If a vaccine dose has been administered during pregnancy, Merck Canada should be contacted to report incident.\textsuperscript{1} The effect of GARDASIL\textsuperscript{®}9 upon embryonic and fetal development has not been assessed in humans.\textsuperscript{1}

### Lactation
GARDASIL\textsuperscript{®}9 may be administered to breastfeeding women. It is not known if GARDASIL\textsuperscript{®}9 vaccine antigens or antibodies induced by vaccine are excreted in human milk.\textsuperscript{2}
References


